

REMARKS

Claims 16-21 and 27-31 are pending. Claims 16-19 and 31 have been amended and new claims 32-40 have been added. Support for these amendments are found throughout the application as originally filed. Specifically, support for the amendment to claim 17 may be found, for example, on page 33, line 30 to page 34, line 11 of the Specification. Support for new claims 32-40 may be found, for example, in Figure 6. Applicants respectfully submit that no new matter has been added and request entry of these amendments.

Claims 16-21 and 27-31 are subject to restriction under 35 U.S.C. §121 for prosecution on the merits because the Examiner contends, that the application contains claims directed to four (4) patentably distinct inventions as follows:

Group I: Claims 16-21 and 31, drawn to a recombinant nucleic acid molecule encoding a modified pneumolysin polypeptide comprising SEQ ID No: 3 with one or more amino acid substitutions, classified in class 536, subclass 23.7;

Group II: Claims 27 and 28, drawn to a method for killing bacteria comprising contacting with antibodies to a modified pneumolysin comprising SEQ ID NO: 3 with one or more amino acid substitutions, classified in class 435, subclass 7.34;

Group III: Claim 29, drawn to a method for immunization of mammals comprising administering a vaccine comprising a modified SEQ ID NO: 3 with one or more amino acid substitutions, classified in class 424, subclass 244.1; and

Group IV: Claim 30, drawn to a method for obtaining modified pneumolysin polypeptide by expressing the mutated nucleic acid molecule in host cells, class 435, subclass 252.3.

Applicants elect Group I (claims 16-21 and 31), the nucleic acid species (c) SEQ ID NO: 1 having a substitution at position 195, and the nucleotide substitution (f) T-583→A with traverse for prosecution on the merits. This election is made without waiver of Applicants' right to file and prosecute to allowance the claims to the non-elected subject matter in a continuation or divisional application claiming priority therefrom. As is set forth in detail below, this election is made with traverse.

Applicants respectfully traverse the restriction requirement as set forth by the Examiner because (1) Applicants are entitled to prosecution of claims covering a reasonable number of species disclosed in an application in accordance with 37 C.F.R. §1.146; and (2) there would be no undue burden on the Examiner to conduct a substantive examination of the claims as related to the embodiments disclosed in the instant application.

The Examiner contends that restriction is appropriate because the groups are not coextensive and have divergent subject matter. Because a search of the claimed subject matter would not be burdensome, Applicants respectfully request withdrawal of the restriction requirement.

According to M.P.E.P. §803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (1) The invention must be independent as claimed; **and**
- (2) There must be serious burden on the Examiner if restriction is not required.

Applicants respectfully submit that (1) all groups of the restricted claims are properly presented in the same application; (2) undue diverse searching would not be required; and (3) all claims should be examined together.

The Examiner has not shown that examination of all the pending claims would require undue searching and/or place a serious burden on the Examiner, which is a requisite showing for proper issuance of a restriction requirement. In fact, Applicants submit that a recombinant nucleic acid molecule encoding a modified pneumolysin polypeptide and a method for obtaining the modified pneumolysin polypeptide by expressing the recombinant nucleic acid molecule would not be unduly burdensome. Claims directed to the recombinant nucleic acid molecule (Group I) and the method of obtaining the polypeptide by expressing the recombinant nucleic acid molecule (Group IV) may be searched together. In fact, there would be overlap. There should not be a serious burden to search a molecule and a method of using the molecule. Accordingly, Applicants respectfully request that at least the claims of Groups I (claims 16-21 and 31) and IV (claim 30) be examined together.

In addition, of the four groups of invention identified by the Examiner, two are in the same class (435). Thus, by searching a single class, the Examiner will have researched two of the four groups. To search prior art in a single class cannot be deemed “undue diverse searching.” So at a minimum, Groups II and IV, should also be examined together. Accordingly, Applicants also respectfully traverse the requirement for restriction at least on the grounds that examining the groups within a single class would not be unduly burdensome.

Furthermore, Applicants respectfully submit that the election of species requirements are improper. According to 37 C.F.R. §1.146, prior to examination, the Examiner may require an election of species to not more than a reasonable number of species before taking further action in the application. In addition, the M.P.E.P. states that “an allowable generic claim may link a reasonable number of species embraced thereby” (see M.P.E.P. §806.04). The Examiner’s position that “one” is the maximum reasonable number of species is inconsistent

with 37 C.F.R. §1.146 and the M.P.E.P. The instant claims present a reasonable number of species embraced thereby. Therefore, Applicants are entitled to examination of all of the pending claims. Applicants respectfully request withdrawal of the election of species requirement.

However, should the Examiner maintain the requirement for election of species, and find the elected species:

- nucleic acid species (c) SEQ ID NO: 1 having a substitution at position 195, or
- the nucleotide substitution (f) T-583→A,

allowable, Applicants respectfully request that the Examiner consider and further examine non-elected nucleic acid species (a), (b) and (d) and nucleotide substitutions (a)-(e) and (g)-(h), respectively.

CONCLUSION

Based on the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the restriction/election of species requirement and allowance of this application.


AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **50-3732**, Order No. 13564.105004. In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **50-3732**, Order No. 13564.105004.

Respectfully submitted,
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By: _____


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